

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

**ASUNCION BUSTAMANTE and HILDA
GABRIEL,**

Plaintiffs,

-against-

**ATRIUM MEDICAL CORPORATION;
MAQUET CARDIOVASCULAR, LLC;
ETHICON INC.; and JOHNSON &
JOHNSON INC.,**

Defendants.

1:18-cv-08395 (ALC)

OPINION & ORDER

ANDREW L. CARTER, JR., United States District Judge:

Plaintiffs Asuncion Bustamante and Hilda Gabriel (collectively, the “Plaintiffs”) bring this action against Defendants Atrium Medical Corporation (“Atrium”), Maquet Cardiovascular, LLC (“MCV”), Ethicon Inc. and Johnson & Johnson Inc. In short, Plaintiffs allege Mr. Bustamante sustained injuries as a result of the implantation of the Atrium ProLite™ Mesh (“ProLite Mesh”) during his hernia repair surgery. *See* Am. Compl., ECF No. 13. Specifically Plaintiffs bring the following claims: Strict Liability Design Defect (Count I), Strict Liability Manufacturing Defect (Count II), Strict Liability Failure to Warn (Count III), Negligence (Count IV), Breach of Warranty (Count V), Punitive Damages (Count VI), Fraudulent Misrepresentation (Count VII), Negligent Misrepresentation (Count VIII), Unjust Enrichment (Count IX) Consumer Fraud (Count X) and Loss of Consortium (XI). Before the Court are Defendants Atrium’s and MCV’s (collectively, the “Defendants”) motions to dismiss Plaintiffs’ claims. After careful consideration, Defendants’ motions to dismiss are **GRANTED**. Additionally, Plaintiffs are **GRANTED** leave to amend their complaint.

BACKGROUND¹

“A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in muscle or connective tissue.” Am. Compl. ¶ 39. Typically, hernias occur near the abdominal wall and at times, manifest as visible protrusions or bulges. *Id.* ¶ 41. Hernias can be treated through hernia repair surgeries. *Id.* ¶ 42. During such procedures, physicians may utilize hernia mesh, which is constructed from synthetic or biologic materials and tissues, to strengthen the repair. *Id.* ¶ 44-45. Common injuries resulting from surgeries using hernia mesh include “pain, infection, adhesion of scar tissue sticking together, blockages that obstruct intestines, internal bleeding, fistula between organs (abnormal organ connection or fusion), seroma or fluid buildup at site, and perforation of other organs.” *Id.* ¶ 48.

Defendant Atrium designed, manufactured, advertised, and sold the ProLite Mesh, which is a mid-weight polypropylene hernia mesh product. *Id.* ¶ 53-56. Atrium also advertised the ProLite Mesh as having “[s]oft knit construction,” “[f]lexib[ility] and comfort[],” and “[s]mooth, laser round edges.” *Id.* ¶ 57-58. Additionally, Atrium represented to Mr. Bustamante and his physician that the ProLite Mesh was safe and effective for hernia repair surgeries. *Id.* ¶ 61. In 2011, Defendant MCV entered into a merger transaction, under which Atrium operates as a business unit of MCV. *Id.* ¶ 8.

On April 21, 2016, Dr. Juan Mestrealcorta performed a hernia repair procedure on Mr. Bustamante. *Id.* ¶ 80. During this procedure, Dr. Mestrealcorta implanted two of Atrium’s ProLite Meshes from Lot No. 400523 in Mr. Bustamante. *Id.* ¶ 81. Since the surgery, Mr. Bustamante has experienced stomach pains, difficulties with walking, limited range of motion,

¹ The following facts are drawn from Plaintiffs’ Amended Complaint and are taken as true for the purposes of these motions to dismiss.

amongst other injuries. *Id.* ¶ 84-86. Mr. Bustamante alleges that as a result of Defendants' misrepresentations and omissions concerning the product's safety, he has suffered economic damages, severe injuries, emotional distress and mental anguish. *Id.* ¶ 87-88.

STANDARD OF REVIEW

When considering a motion to dismiss under Federal Rules of Civil Procedure 12(b)(6), a court should "draw all reasonable inferences in [the plaintiff's] favor, assume all well-pleaded factual allegations to be true, and determine whether they plausibly give rise to an entitlement to relief." *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011) (internal quotation marks omitted). Thus, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The Court's function on a motion to dismiss is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." *Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir. 1985). The Court should not dismiss the complaint if the plaintiff has stated "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Moreover, "the tenet that a court must accept a complaint's allegations as true is inapplicable to threadbare recitals of a cause of action's elements, supported by mere conclusory statements." *Id.* at 663.

DISCUSSION

I. The Court Lacks Personal Jurisdiction Over MCV

On a motion to dismiss, "the plaintiff bears the burden of establishing that the court has jurisdiction over the defendant." *DiStefano v. Carozzi N. Am., Inc.*, 286 F.3d 81, 84 (2d

Cir. 2001) (citation omitted); *see also In re Terrorist Attacks on Sept. 11, 2001*, 714 F.3d 659, 673 (2d Cir. 2013); Fed. R. Civ. Pro. 12(b)(2). Prior to discovery, a plaintiff may survive scrutiny of personal jurisdiction over a defendant by presenting, “[a] prima facie case [that] requires . . . fact specific allegations or evidence showing that activity that constitutes the basis of jurisdiction has taken place.” *Chirag v. MT Marida Marguerite Schiffahrts*, 604 F. App'x 16, 19 (2d Cir. 2015) (citing *Jazini v. Nissan Motor Co.*, 148 F.3d 181, 185 (2d Cir. 1998)); *see also In re Terrorist Attacks*, 714 F.3d at 673 (citation omitted) (“In order to survive a motion to dismiss for lack of personal jurisdiction, a plaintiff must make a prima facie showing that jurisdiction exists.”). All jurisdictional allegations “are construed in the light most favorable to the plaintiff and doubts are resolved in the plaintiff’s favor[.]” *A.I. Trade Fin., Inc. v. Petra Bank*, 989 F.2d 76, 79-80 (2d Cir. 1993). However, the court “will not draw argumentative inferences in the plaintiffs favor” and need not “accept as true a legal conclusion couched as a factual allegation.” *In re Terrorist Attacks*, 714 F.3d at 673 (citations omitted); *see also Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 673 F.3d 50, 59 (2d Cir. 2012).

In cases with diversity jurisdiction, the Court must engage in a two-part analysis to determine whether personal jurisdiction exists. *See Kernan v. Kurz-Hastings, Inc.*, 175 F.3d 236, 240 (2d Cir. 1999). First, the Court “must determine whether the plaintiff has shown that the defendant is amenable to service of process under the forum state’s laws; and second, it must assess whether the court’s assertion of jurisdiction under these laws comports with the requirements of due process.” *Id.* (citing *Metropolitan Life Ins. Co. v. Robertson-Ceco Corp.*, 84 F.3d 560, 566 (2d Cir.1996)). Here, Plaintiffs argue they can demonstrate both general jurisdiction under New York C.P.L.R. § 301 and specific jurisdiction under C.P.L.R. § 302.

a. General Jurisdiction

“General jurisdiction in New York is provided for in C[.]P[.]L[.]R[.] §] 301, which allows a court to exercise ‘such jurisdiction over persons, property, or status as might have been exercised heretofore.’” *Hartford Fire Ins. Co. v. Maersk Line*, No. 18-CV-121, 2019 WL 4450639, at *5 (S.D.N.Y. Sept. 17, 2019) (quoting *Aybar v. Aybar*, 169 A.D.3d 137, 143 (2d Dep’t 2019)). Since “the Supreme Court’s guidance on due process in *Daimler AG v. Bauman*, 571 U.S. 117, 139 (2014) . . . New York exercises general personal jurisdiction only if ‘the corporation’s affiliations with the state are so continuous and systematic as to render them essentially at home in the forum State.’” *Id.*

Additionally, federal due process permits general jurisdiction “when [the defendant’s] affiliations with the State are so ‘continuous and systematic’ as to render them essentially at home in the forum State.” *Goodyear Dunlop Tires Ops., S.A. v. Brown*, 564 U.S. 915, 919 (2011). Thus, “[a]side from ‘an exceptional case’ . . . a corporation is at home . . . only in a state that is the company’s formal place of incorporation or its principal place of business.” *Gucci Am., Inc. v. Weixing Li*, 768 F.3d 122, 135 (2d Cir. 2014) (quoting *Daimler*, 134 S. Ct. at 761, n.19).

In this case, Plaintiffs allege MCV is organized under the laws of New Jersey and maintains its principal place of business in New Jersey. Accordingly, MCV is not at home in New York and for this reason, the Court cannot exercise general jurisdiction over it. In addition, Plaintiffs’ argument that MCV’s registration in New York allows this Court to exercise general jurisdiction over it is unavailing. As the New York Appellate Division recently held in *Aybar v. Aybar*, “a corporate defendant’s registration to do business in New York and designation of the secretary of state to accept service of process in New York does not constitute consent by the

corporation to submit to the general jurisdiction of New York for causes of action that are unrelated to the corporation's affiliations with New York." 93 N.Y.S.3d at 170; *see also Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 639 (2d Cir. 2016) (finding that an interpretation of Connecticut's business registration statute constituting consent to general jurisdiction "risk[ed] unravelling the jurisdictional structure envisioned in *Daimler* and *Goodyear*"); *Carson v. W. Express, Inc.*, No. 19 CIV. 2227, 2019 WL 6050730, at *3 (S.D.N.Y. Nov. 14, 2019) (citing *Hartford Fire Ins.*, 2019 WL 4450639, at *6) ("determin[ing] that the designation of an agent for service alone cannot provide this Court with general personal jurisdiction over Defendants."); *Famular v. Whirlpool Corp.*, 2017 WL 2470844, at *4-5 (S.D.N.Y. June 7, 2017) ("[D]espite the uncertain status of the law in this area, a foreign defendant is not subject to the general personal jurisdiction of the forum state merely by registering to do business with the state, whether that be through a theory of consent by registration or otherwise.").

b. Specific Jurisdiction

Pursuant to New York's long-arm statute, a non-domiciliary is subject to specific jurisdiction in New York if it

commits a tortious act without the state causing injury to person or property within the state, except as to a cause of action for defamation of character arising from the act, if he (i) regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in the state, or (ii) expects or should reasonably expect the act to have consequences in the state and derives substantial revenue from interstate or international commerce[.]

C.P.L.R. § 302 (a)(3). "[P]roof of one transaction in New York is sufficient to invoke jurisdiction, even though the defendant never enters New York, so long as the defendant's activities here were purposeful and there is a substantial relationship between the transaction and

the claim asserted.” *Chloe v. Queen Bee of Beverly Hills, LLC*, 616 F.3d 158, 170 (2d Cir. 2010) (quoting *Kreutter v. McFadden Oil Corp.*, 522 N.E.2d 40, 43 (1988)).

Additionally, to comport with federal due process requirements, a plaintiff must plausibly allege minimum contacts showing the defendant “purposefully directed his activities” at the forum and the litigation “result[ed] from alleged injuries that arise out of or relate to those activities.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985) (citations and internal quotation marks omitted). Stated differently, “the defendant’s suit-related conduct must create a substantial connection with the forum State.” *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014); *accord Goodyear*, 564 U.S. at 923-24. Minimum contacts may be established where a defendant “purposefully availed itself of the privilege of doing business in the forum and could foresee being haled into court there.” *Licci*, 732 F.3d at 170 (citations omitted). A defendant also establishes minimum contacts with the forum where “the defendant took ‘intentional, and allegedly tortious, actions . . . expressly aimed’ at the forum.” *In re Terrorist Attacks*, 714 F.3d at 674 (quoting *Calder v. Jones*, 465 U.S. 783, 789 (1984)) (alteration in original).

In their opposition brief, Plaintiffs argue MCV is subject to the Court’s specific jurisdiction because it bought ProLite Mesh products from Atrium between January 2014 and October 2017 and then in turn sold them to Maquet Cardiovascular US, LLC, where Mr. Bustamante’s devices were bought. Plaintiffs argue this puts MCV within the distribution chain; therefore, it is liable for tortious conduct emanating from that sale. However, Plaintiffs fail to include such allegations in their Amended Complaint. Instead, the facts alleged indicate that MCV was the alter ego, successor and agent of Atrium as the result of a merger transaction. *See* Am. Compl. ¶ 8–21. Plaintiffs’ jurisdictional allegations in this respect are largely conclusory

and fail to plausibly allege specific jurisdiction over MCV. *See Iqbal*, 556 U.S. at 678.

Furthermore, Plaintiffs abandon these claims in their opposition brief.

With that said, even if Plaintiffs had alleged that MCV was an intermediary in the chain of distribution, these facts would fail to plausibly allege specific jurisdiction consistent with due process requirements. Although specific jurisdiction can be established through a “stream of commerce” theory, “the precise requirements of that theory are unsettled.” *RegenLab USA LLC v. Estar Techs. Ltd.*, 335 F. Supp. 3d 526, 544 (S.D.N.Y. 2018) (internal quotations citations omitted). The Supreme Court, in *J. McIntyre Mach., Ltd. v. Nicastro*, addressed the theory of stream of commerce but did not announce a majority opinion. 564 U.S. 873 (2011). Justice Kennedy asserted that a defendant’s “predict[ion] that its goods will reach the forum state” is insufficient to establish minimum contacts; the defendant must be “said to have targeted the forum.” *McIntyre*, 564 U.S. at 882. Concurring, Justice Breyer concluded that the outcome was “determined by our precedents,” and “[n]one of our precedents finds that a single isolated sale” satisfies minimum contacts. *Id.* at 888 (Breyer, J. concurring). Justice Breyer emphasized that the facts presented revealed no “‘regular . . . flow’ or ‘regular course’ of sales” in the forum state and that there was “no ‘something more,’ such as special state-related design, advertising, advice, marketing, or anything else.” *Id.* at 889 (Breyer, J. concurring). “As the narrowest opinion, Justice Breyer’s holding—that the law remains the same after *McIntyre*—controls.” *RegenLab USA LLC*, 335 F. Supp. 3d at 544 (internal quotations and citations omitted).

Without additional allegations that MCV targeted New York or had a regular or high volume of sales in the state, the fact that MCV served as an intermediary in the distribution chain is insufficient to establish specific jurisdiction over it. *See Ikeda v. J. Sisters 57, Inc.*, No. 14 Civ.

3570, 2015 WL 4096255, at *5, *8 (S.D.N.Y. July 6, 2015) (determining Plaintiff failed to sufficiently allege minimum contacts to support the exercise of personal jurisdiction where plaintiffs failed to allege “any additional products manufactured by [the non-domiciliary defendant] reached the New York market, let alone ventured to estimate the volume of [defendant’s] goods that make their way into the state”); *cf. State Farm Fire & Cas. Co. v. Swizz Style, Inc.*, 246 F. Supp. 3d 880, 889 (S.D.N.Y. 2017) (finding Plaintiff sufficiently alleged minimum contacts for specific jurisdiction based on the non-domiciliary Defendant’s significant volume of sales in and targeting of the forum state). Accordingly, the Court finds Plaintiffs have not established personal jurisdiction as to MCV, so it must be dismissed from this action.

II. Plaintiffs Have Otherwise Failed to State a Cognizable Claim

a. Strict Liability and Negligence Claims

Here, Plaintiffs bring product liability claims under both strict liability—specifically, counts I, II and II—and negligence—specifically, count IV. Under New York law, strict liability and negligence are functionally equivalent. *See, e.g., Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (citing *Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 129, (1981)) (analyzing strict liability and negligent manufacturing defect claims together); *Estrada v. Berkel Inc.*, 789 N.Y.S.2d 172, 173 (N.Y. App. Div. 2d Dep’t 2005) (“Where liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent[.]”) (citation omitted); *Searle v. Suburban Propane Div. of Quantum Chem. Corp.*, 700 N.Y.S.2d 588, 591 (N.Y. App. Div. 3d Dep’t 2000) (“[I]n a design defect case, there is almost no difference between a prima facie case in negligence and one in strict liability.”). Accordingly, the Court will analyze Plaintiffs’ strict liability and negligence claims of design defects, manufacturing defects, and failure to warn together.

i. Design Defect

“Under New York law, a plaintiff establishes a *prima facie* case of products liability for a design defect by showing: (1) that the product, as designed, posed a substantial likelihood of harm; (2) that it was feasible for the manufacturer to design the product in a safer manner; and (3) that the defective design was a substantial factor in causing plaintiffs injury.” *See Am. Guarnatee & Liab. Ins. Co. v. Cirrus Design Corp.*, No. 09-CV-8357, 2010 WL 5480775, at *3 (S.D.N.Y. Dec. 30, 2010) (citing *Tuosto v. Philip Morris USA Inc.*, 672 F.Supp.2d 350, 364 (S.D.N.Y. 2009)). “Although a plaintiff need not possess specialized scientific or technical knowledge at the pleading stage, courts have routinely dismissed strict products liability claims premised on a design defect where the plaintiff has failed to plead that it was feasible to design the product in a safer manner (‘a feasible alternative design’).” *Kennedy v. Covidien, LP*, No. 18-CV-01907, 2019 WL 1429979, at *3 (S.D.N.Y. Mar. 29, 2019) (citing *DiBartolo v. Abbott Labs.*, 914 F.Supp.2d 601, 622-23 (S.D.N.Y. 2012)); *See also Am. Guarnatee*, 2010 WL 5480775, at *3 (citing *Rypkema v. Time Mfg. Co.*, 263 F.Supp.2d 687, 692 (S.D.N.Y.2003)) (“When applying this risk-utility balancing test, a plaintiff is required to prove the existence of a feasible alternative design which would have prevented the accident.”); *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 108 (1983) (“The plaintiff, of course, is under an obligation to present evidence that the product, as designed, was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner.”).

Here, Plaintiffs have failed to adequately plead a claim of defective design because they have not sufficiently pled the existence of a feasible alternative design. In fact, Plaintiffs’ Amended Complaint includes conclusory statements such as the following: “[a]lternative designs for hernia mesh products and/or procedures existed that were and/or are less dangerous and

equally, i[f] not more, effective,” “[a]lternative designs for hernia mesh products and/or procedures existed that were and/or are less dangerous and equally, i[f] not more, effective, including the use of polycarbonate and polystyrene as alternatives,” and “[s]afer and more effective alternatives to hernia mesh exist and have existed since the introduction of hernia mesh products into the market . . . [including] the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair.” Am. Compl., ¶ 52, 107-108. “Simply asserting that a feasible alternative design exists—without pleading any supporting facts—is not sufficient to plead a defective design claim or to put Defendant on notice as to what that design might be.” *Green v. Covidien LP*, No. 18 CIV. 2939, 2019 WL 4142480, at *3 (S.D.N.Y. Aug. 30, 2019).

Furthermore, even if Plaintiffs had sufficiently shown that using polycarbonate and polystyrene materials would be technically and economically feasible and result in a safer design, these claims would fail. As courts in this circuit have noted, “alleging that the product should not be used at all is insufficient to satisfy the feasible alternative design element.” *Green*, 2019 WL 4142480, at *3 (citing *Kennedy*, 2019 WL 1429979, at *4); *see also Dunham v. Covidien LP*, No. 19 CIV. 2851, 2019 WL 2461806, at *2 (S.D.N.Y. May 22, 2019) (dismissing a similar design defect claim in a hernia mesh products liability case).

ii. Manufacturing Defect

Under New York Law, “[t]o plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of ‘some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,’ and that the defect was the cause of plaintiff’s injury.” *Am. Guarnatee*, 2010 WL 5480775, at *3 (quoting *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F.Supp.2d 53, 85 (S.D.N.Y.2001)). “Where the plaintiff does not allege a specific flaw

in the defective unit, New York law allows the use of circumstantial evidence to establish a manufacturing defect when plaintiff can show that the product did not perform as intended and excludes all other causes for the product failure that are not attributable to the defendant.” *Kennedy*, 2019 WL 1429979, at *4 (citing *Goldin v. Smith & Nephew, Inc.*, No. 12-civ-9217, 2013 WL 1759575 *3 (S.D.N.Y. April 24, 2013)).

In this case, Plaintiffs have failed to allege a manufacturing defect. In fact, Plaintiffs have failed to identify what specific component(s) of the devices were defective and have failed to adequately allege any deviations from the manufacturing process, improper workmanship, or defective materials. Plaintiffs additionally cannot use Mr. Bustamante’s injuries as circumstantial evidence to establish a manufacturing defect. As Plaintiffs indicate, Mr. Bustamante’s injuries are consistent with “common injuries” and are “known side effects” caused by hernia repair surgeries using mesh products. Am. Compl. ¶¶ 48, 50. It therefore cannot be said that his ProLite Meshes did not perform as intended. *See Kennedy*, 2019 WL 1429979, at *4 (dismissing a similar manufacturing defect claim in a hernia mesh products liability case and finding that Plaintiff’s common injuries led “to the inference that the product was manufactured and performed as intended”); *see also Dunham*, 2019 WL 2461806, at *2; *Green*, 2019 WL 4142480, at *3-4.

iii. Failure to Warn

In order to recover under a failure to warn theory, a claimant must show: “(1) that a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of harm.” *Am. Guarntee*, 2010 WL 5480775, at *3 (quoting *Colon ex rel. Molina*, 199 F. Supp. 2d at 84). As part of satisfying those elements, a plaintiff is “required to prove that the product did

not contain adequate warnings.” *Mulhall v. Hannafin*, 841 N.Y.S.2d 282, 285 (N.Y. App. Div. 1st Dep’t 2007). Generally, whether a warning is adequate is an issue of fact to be determined at trial. *Figueroa v. Boston Sci. Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003) (quoting *Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991)). “There are several important considerations that directly affect the adequacy of a warning, including the location and conspicuousness of the warning and the method in which the warning is communicated to the ultimate user.” *Anderson v. Hedstrom Corp.*, 76 F. Supp. 2d 422, 440 (S.D.N.Y. 1999).

Here, Plaintiffs’ allegations of inadequate warnings are, for the most part, conclusory. For example, Plaintiffs allege the device “contained warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the product” and that “[t]he warnings . . . were ambiguous or were not sufficient, accurate or clear.” Am. Compl. ¶ 98, 104. Plaintiffs further allege, Atrium’s website “has a very minimal amount of advertisement and information for the general public.”² *Id.* ¶ 135. Notably absent from Plaintiffs’ Amended Complaint is the exact language of the warnings contained on the device. The Court therefore finds, Plaintiffs’ “allegations do not include any factual content regarding . . . how the provided warnings and information failed to [] accurately reflect[] reality; they do not provide a plausible basis to support an inference that [Defendant] misrepresented anything.” *Green*, 2019 WL 4142480, at *5 (S.D.N.Y. Aug. 30, 2019) (quoting *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 576 (E.D.N.Y. 2012)); *see also Dunham*, 2019 WL 2461806, at *3; *Kennedy*, 2019 WL 1429979, at *5. Accordingly, this claim must be dismissed.

² To support this allegation, Plaintiffs cite to Atrium’s website. *See* Am. Compl. ¶ 99, (citing <http://www.atriummed.com/en/biosurgery/prolite.asp>). However, this webpage is no longer accessible.

b. Fraud Based Claims

i. Fraudulent Misrepresentation

To state a claim for fraudulent misrepresentation under New York law, a plaintiff must show: “(1) the defendant made a material false representation, (2) the defendant intended to defraud the plaintiffs thereby, (3) the plaintiffs reasonably relied upon the representation, and (4) the plaintiffs suffered damage as a result of their reliance.” *Swersky v. Dreyer & Traub*, 643 N.Y.S.2d 33, 36 (N.Y. App. Div. 1st Dep’t 1996). To satisfy the element of damage, a Plaintiff must establish proximate causation. *In re Fosamax Prods. Liab. Litig.*, 924 F. Supp. 2d 477, 489 (S.D.N.Y. 2013); *see, e.g., Hunt v. Enzo Biochem, Inc.*, 471 F. Supp. 2d 390, 399-400 (S.D.N.Y. 2006) (stating that a claim of common law fraud under New York law “requires a showing of proximate causation”).

Additionally, fraudulent misrepresentation claims are subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b), which provides that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b); To comply with Rule 9(b), a complaint alleging fraudulent misrepresentation under New York law must: “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006) (quoting *Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993)). “A statement is ‘fraudulent’ if it was falsely made, or caused to be made, with the intent to deceive.” *United States v. Sabbeth*, 262 F.3d 207, 217 (2d Cir. 2001) (citations omitted).

Plaintiffs’ fraudulent misrepresentation claims largely fall into two categories. First, Plaintiffs allege Defendants fraudulently made misrepresentations from 2009 to present,

concerning the safety of the Prolite Mesh. *See* Am. Compl. ¶ 166. Second, Plaintiffs allege from 2009 to present Defendant omitted material information from their website, instructions for use, literature to the medical community, advertisements, and brochures, concerning the risks associated with the device. *See id.*³ The Court finds that both types of claims fail.

As an initial matter, Plaintiffs' allegations premised upon affirmative misrepresentations fail to sufficiently satisfy Rule 9(b). In particular, Plaintiffs' Amended Complaint only specifies affirmative statements from the product brochure. *See* Am. Compl. ¶ 166 ("Atrium's website explicitly warrants Defendants' device as having 'See-thru clarity', 'Flexible and comfortable,' and 'smooth.'"). However, Plaintiffs fail to explain why the statements are fraudulent and therefore these claims must be dismissed. *See Dunham*, 2019 WL 2461806, at *4 ("Absent any factual support for the conclusion that [the defendant's] statements regarding the hernia mesh were fraudulent, the fraudulent misrepresentation claim cannot stand."); *see also Green*, 2019 WL 4142480, at *9; *Kennedy*, 2019 WL 1429979, at *7.

In addition, Plaintiffs' allegations premised on omissions fail to allege reliance. The Amended Complaint lacks details regarding whether and how Mr. Bustamante and his physician reviewed and relied upon Defendants' statements. Instead, Plaintiffs make conclusory allegations such as, "Plaintiff ASUNCION BUSTAMANTE, through his physicians and healthcare providers, and his physicians reasonably relied upon Defendants' misrepresentations and omissions regarding the safety and efficacy of Defendants' hernia mesh product." Am. Compl. ¶ 183. Because Plaintiffs fail to provide factual support showing what information Mr. Bustamante and his treating physician received and whether or not they relied on those statements, Plaintiffs have failed to sufficiently plead a claim of fraudulent misrepresentations based on omissions.

³ Again, Plaintiffs support their allegations by citing to various webpages on Defendants' website. *See* Am. Compl. ¶¶ 166. With the exception of the Product brochure, the remaining webpages are no longer available. *Id.*

Quintana v. B. Braun Med. Inc., No. 17-CV-06614 (ALC), 2018 WL 3559091, at *8 (S.D.N.Y. July 24, 2018), *appeal withdrawn*, No. 18-2495, 2018 WL 6167320 (2d Cir. Oct. 19, 2018). For the aforementioned reasons, Plaintiffs' fraudulent misrepresentation claims are dismissed.

ii. Negligent Misrepresentation

To state a claim for negligent misrepresentation, a plaintiff must show that:

the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that he or she should have known was incorrect; (3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff reasonably relied on it to his or her detriment.

Eaves v. Designs for Fin., Inc., 785 F. Supp. 2d 229, 254 (S.D.N.Y. 2011) (quoting *Hydro Investors, Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 20 (2d Cir. 2000)).

"A plaintiff alleging negligent misrepresentation must establish reliance upon a false statement or material misrepresentation or omission, and the learned intermediary rule eliminates the possibility of any such reliance." *Amos v. Biogen Idec Inc.*, 249 F. Supp. 3d 690, 697 (W.D.N.Y. 2017) (internal citations and quotations marks omitted). Again, because here Plaintiffs fail to sufficiently allege the Defendants' made false representations and fail to plausibly allege what misrepresentations Mr. Bustamante or his physician relied on, their negligent misrepresentation claims are dismissed. *See Glidepath Holding B. V. v. Spherion Corp.*, 590 F. Supp. 2d 435, 459 (S.D.N.Y. 2007) ("[W]hether a plaintiff has adequately pleaded justifiable reliance can be a proper subject for a motion to dismiss in certain circumstances."); *see also Kennedy*, 2019 WL 1429979, at *7 (S.D.N.Y. Mar. 29, 2019) (dismissing a negligent representation claim because "Plaintiff d[id] not provide any factual basis for his conclusion that Defendant's risk disclosures for [the hernia mesh product] were misrepresentations or inaccurate.").

iii. Consumer Fraud

Section 349 of New York General Business Law makes unlawful “[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state.” N.Y. Gen. Bus. Law. § 349(a). Section 350 prohibits “[f]alse advertising in the conduct of any business.” N.Y. Gen. Bus. Law § 350. To state a claim for deceptive practices under either section, a plaintiff must show: “(1) that the act, practice or advertisement was consumer-oriented; (2) that the act, practice or advertisement was misleading in a material respect, and (3) that the plaintiff was injured as a result of the deceptive practice, act or advertisement.” *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 524-25 (S.D.N.Y. 2003). To state a claim under the statute, a plaintiff must, “as a threshold matter, . . . charge conduct of the defendant that is consumer-oriented,” *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, defined as conduct that “potentially affect[s] similarly situated consumers.” 85 N.Y.2d 20, 745 (N.Y. 1995). Consumer-oriented conduct does not require a repetition or pattern of deceptive conduct, but a plaintiff must nevertheless “demonstrate that the acts or practices have a broader impact on consumers at large.” *Id.* at 744. In addition, “[t]o properly allege causation, a plaintiff must state in his complaint that he has seen the misleading statements of which he complains before he came into possession of the products he purchased.” *Goldemberg v. Johnson & Johnson Consumer Cos., Inc.*, 8 F. Supp. 3d 467, 480 (S.D.N.Y. 2014) (citing, *inter alia*, *Gale v. Intl Bus. Machs. Corp.*, 9 A.D.3d 446, 781 N.Y.S.2d 45 (N.Y. App. Div. 2d Dep’t 2004)).

In this case, similar to the discussions on fraudulent misrepresentation and negligent misrepresentation, Plaintiffs’ failure to allege facts supporting the conclusion that the Defendants made misrepresentations and their failure to allege either Mr. Bustamante or his physician relied

on these statements is fatal to their consumer fraud claim; these claims therefore are dismissed. *Dunham*, 2019 WL 2461806, at *5 (dismissing a consumer fraud claim where Plaintiff did “not allege sufficient facts to support a conclusion that any of [the defendant’s] representations were deceptive or false.”).

c. Breach of Warranty

i. Express Breach of Warranty

An express warranty is formed by “[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods’ or ‘any description of the goods’ that is ‘part of the basis of the bargain.’” *Williamson*, 2013 U.S. Dist. LEXIS 104445, 2013 WL 3833081, at *8 (quoting N.Y. U.C.C. § 2-313). While it is not required to use formal words such as “warrant” or “guarantee,” nor allege that the speaker had a specific intention to make a warranty, “an affirmation merely of the value of the goods or a statement purporting to be merely the seller’s opinion or commendation of the goods does not create a warranty.” *Id.* “To establish the breach of an express warranty, the plaintiff must show that there was an ‘affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase’ and that the warranty was relied upon to the plaintiff’s detriment.” *Goldin*, 2013 WL 1759575, at *6 (citing *Barrett v. Black & Decker (U.S.) Inc.*, No. 06-CV-1970, 2008 WL 5170200, at *12 (S.D.N.Y. Dec. 9, 2008)).

In this case, Plaintiffs allege the Defendants warranted that the ProLite Mesh product was safe, effective and adequately tested in medical trials. *See e.g.*, Am. Compl. ¶¶ 157, 171-172. Plaintiffs however fail to identify a specific warranty made by Defendants that was relied upon by Plaintiffs. *Kennedy*, 2019 WL 1429979, at *6 (citing *Viania v. Zimmer, Inc.*, No. 2:17-cv-164, 2017 WL 5714725, at *5 (E.D.N.Y. Nov. 27, 2017)) (Plaintiff’s “characterization of Defendant’s

marketing material as generally implying that [the hernia mesh product] was ‘safe and effective’ does not identify any specific actionable conduct or statement on behalf of Defendant.”); *see also Dunham v. Covidien LP*, 2019 WL 2461806, at *5. Accordingly, Plaintiffs express breach of warranty claim must be dismissed.

ii. Implied Breach of Warranty

Under the New York Uniform Commercial Code, “[t]o establish that a product is defective for purposes of a breach of implied warranty of merchantability claim, a plaintiff must show that the product was not reasonably fit for its intended purpose, an inquiry that focuses on the expectations for the performance of the product when used in the customary, usual, and reasonably foreseeable manners.” *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp. 2d 406, 420-21 (S.D.N.Y. 2011) (citing *O’Sullivan v. Duane Reade, Inc.*, 27 Misc. 3d 1215[A], 910 N.Y.S.2d 763, 2010 NY Slip Op 50757[U] at *6 [N.Y. Sup. Ct. 2010]). For reasons articulated above, Plaintiffs fail to allege that the ProLite Meshes implanted in Mr. Bustamante were not reasonably fit for their intended purpose. “Although the complaint alleges that Mr. [Bustamante] has experienced stomach pain . . . following his procedures, those allegations of common consequences of hernia surgeries do not show that [Defendants’] products were unsafe for hernia mesh repairs.” *Dunham*, 2019 WL 2461806, at *5. *See also Kennedy*, 2019 WL 1429979, at *6 (dismissing an implied breach of warranty claim where plaintiff did “not allege[] or argue[] a factual basis for concluding that the product was not minimally safe for its expected purpose despite some disclosed risks.”). Plaintiffs’ implied breach of warranty claim therefore must also be dismissed.

d. Unjust Enrichment

“To prevail on a claim for unjust enrichment in New York, a plaintiff must establish (1) that the defendant benefitted; (2) at the plaintiff’s expense; and (3) that equity and good conscience require restitution.” *Beth Israel Med. Ctr. v. Horizon Blue Cross & Blue Shield of New Jersey, Inc.*, 448 F.3d 573, 586 (2d Cir. 2006) (citing *Kaye v. Grossman*, 202 F.3d 611, 616 (2d Cir.2000)) (internal quotation marks omitted). Because Plaintiffs have neither plausibly pleaded facts supporting a finding that the ProLite Meshes implanted in Mr. Bustamante were defective nor have they pled that the sale of said product was induced by misrepresentations or omissions, restitution is not appropriate. *See Kennedy*, 2019 WL 1429979, at *8 (dismissing a Plaintiff’s unjust enrichment claim in a case involving a hernia mesh because he “ha[d] not plausibly pleaded facts demonstrating that Defendant’s product was defective or that the sale was induced through a misrepresentation, and thus there is no equitable basis for a requiring restitution.”); *see also Green*, 2019 WL 4142480, at *9; *Dunham*, 2019 WL 2461806, at *6.

e. Punitive Damages

In light of the Court’s dismissal of Plaintiffs’ other claims, it is unnecessary for the Court to reach Defendants’ remaining contentions regarding dismissal of Plaintiffs’ prayer for punitive damages, which is not a self-sustaining claim. *ACR Sys., Inc. v. Woori Bank*, 232 F. Supp. 3d 471, 479 (S.D.N.Y. 2017) (citing *Martin v. Dickson*, 100 Fed.Appx. 14, 16 (2d Cir. 2004)); *see also Green*, 2019 WL 4142480, at *10; *Kennedy*, 2019 WL 1429979, at *8.

f. Loss of Consortium

Similarly, the Court need not address Plaintiffs’ claims for loss of consortium. *See Dunham*, 2019 WL 2461806, at *6 (S.D.N.Y. May 22, 2019) (citing *Jordan v. Lipsig, Sullivan, Mollen & Liapakis, P.C.*, 689 F. Supp. 192, 196 (S.D.N.Y. 1988)) (“A claim for loss of

consortium or services is a derivative action, and in the common law of New York, does not exist ‘independent of the injured spouse’s right to maintain an action for injuries sustained.’”).

III. Leave to Amend

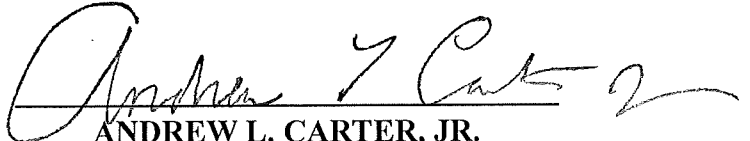
Pursuant to Federal Rules of Civil Procedure 15(a)(1) a party may amend its complaint once without leave of court up to 21 days after the service of either a responsive pleading or various Fed. R. Civ. P. 12 motions. *See* Fed. R. Civ. P. 15(a)(1). After that time has expired, any amendment requires the consent of the opposing parties or leave of court. *See* Fed. R. Civ. P. 15(a)(2). Rule 15(a)(2) states “the court should freely give leave when justice so requires.” *Id.* The Supreme Court has instructed that “this mandate is to be heeded.” *Foman v. Davis*, 371 U.S. 178, 182 (1962). However, it is ultimately “within the sound discretion of the court whether to grant leave to amend.” *John Hancock Mut. Fife Ins. Co. v. Amerford Int’l Corp.*, 22 F.3d 458, 462 (2d Cir. 1994) (citing *Foman*, 371 U.S. at 178). Where “the moving party has unduly delayed or acted in bad faith, the opposing party will be unfairly prejudiced if leave is granted, or the proposed amendment is futile” courts in this circuit have denied motions to amend a complaint. *Agerbrink v. Model Serv. LLC*, 155 F. Supp. 3d 448, 452 (S.D.N.Y. 2016). The Court finds that Defendants have not made a showing of bad faith or prejudice. Accordingly, Plaintiffs are **GRANTED** leave to amend their Complaint.

CONCLUSION

For the foregoing reasons, Defendants' motions to Dismiss are **GRANTED**. However, Plaintiffs are **GRANTED** leave to amend their complaint. Plaintiffs shall submit an amended complaint to the Court on or before **March 5, 2020**.

SO ORDERED.

Dated: February 6, 2020
New York, New York



ANDREW L. CARTER, JR.
United States District Judge